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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:	Patent Application of Jean-Pierre Sachetto *et al.*	: Group Art Unit: 1614
Appln. No.:	**10/587,201**	: Examiner: HUGHES, Alicia R.
Filed:	15 May 2007	: Attorney Docket No: SACH3001/ESS
For:	TYPE A GELATIN CAPSULE CONTAINING PUFA IN FREE ACID FORM	:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF THOMAS BUSER UNDER 37 C.F.R § 1.132

I, Thomas Buser, of Tillotts Pharma AG solemnly declare and affirm the following:

1. I am a co-inventor of the above-identified application.
2. I am currently the Director of New Product Development at Tillotts Pharma AG. I apprenticed at Sandoz in Basel, Switzerland. I have four (4) years chemical/pharmaceutical production experience and five (5) years chemical formulation development experience. Furthermore, I have served as head of pharmaceutical development of Tillotts Pharma AG for sixteen (16) years. Based on my at least 25 years of extensive experience in chemical and pharmaceutical development, I am well qualified to comment and provide opinion in the matters currently under question.

3. The following paragraphs contain my comments and opinions concerning the United States Patent Office's ("The Office's") rejection of claims 1-10, 16-22 and 35-41 in the 18 February 2010 Non-Final Office Action (hereafter referred to as the Office Action) of the above-captioned patent application.

4. I have read the Office Action and I understand that the Office has rejected claims 1-10 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 5,502,077 ("Breivik") in view of U.S. Pat. No. 4,935,243 ("Borkan") and in further view of U.S. Pat. Pub. No. 2003/0064074 ("Chang") and on the grounds of nonstatutory obviousness-type double patenting over claims 1-12 and 14-17 of U.S. Pat. No. 5,792,795 ("Buser") in view of Borkan and in further view of Chang. (Office Action, dated Feb. 18, 2010, pgs. 3-9).

5. I have read the specification of the above-captioned patent application and the claims shown in Exhibit A.

6. I have read Breivik, Borkan, and Chang.

7. As set forth below, the inventive composition provides unexpected and surprising results compared to the individual and/or combined components disclosed in Breivik, Borkan and Chang.

8. At the time of invention, one of ordinary skill in the art would have understood Type A gelatin and Type B gelatin to exhibit similar properties and have similar chemical structures. Similarly, at the time of invention, one of ordinary skill in the art would have understood Bovine gelatin and Porcine gelatin to be interchangeable because they exhibit similar properties.

9. Indeed, the Examiner, based on Borkan (Col. 3, Lines 40-46), stated "gelatin types, between Type A and Type B are interchangeable." (Office Action, dated Feb. 18, 2010, pg. 7).

10. Under certain conditions, soft gelatin capsules can harden. The hardening is due to the chemical interaction between the omega 3 polyunsaturated fatty acid formulation and the gelatin itself. Hardened capsules exhibit prolonged disintegration times and, when administered orally, may not disintegrate in the appropriate part of the digestive tract. In other words, once a gelatin becomes hardened, soft gelatin capsules made from that gelatin may no longer be therapeutically effective. Accordingly, the hardening effect is

detrimental to the shelf life of the capsules.

11. When stored at 40°C, skin or "pellicle" is rapidly formed at the interface between an omega-3 polyunsaturated fatty acid in free acid form and the following soft gelatin capsules: Bovine gelatin Type B, Bovine gelatin Type A and Fish gelatin Type A. The formation of the skin led to a hardening of each of these gelatins, which, thereby, prolonged their disintegration time and reduced their shelf life.

12. Based on this information, at least at the time of invention, one of ordinary skill in the art would have expected Porcine Type A gelatin that encapsulates an omega-3 polyunsaturated fatty acid in free acid form to react in a similar matter, i.e., that skin would rapidly form at the interface between the omega-3 polyunsaturated fatty acid in free acid form and Porcine Type A gelatin, that disintegration time would be prolonged and that shelf life would be reduced. However, when stored at 40°C, no skin or "pellicle" is formed at the interface between an omega-3 polyunsaturated fatty acid in free acid form and a Porcine gelatin Type A capsule. Disintegration time remains stable and, thereby, shelf life is prolonged. Similar results occur when the gelatins are stored at 25°C and 30°C.

13. Stability profiles of Bovine gelatin Type B, Bovine gelatin Type A, Fish gelatin Type A, and Porcine gelatin Type A at 25°C, 30°C and 40°C are shown in Exhibits B - D. Given that at least Bovine Type A gelatin and Porcine Type A gelatin would be expected to behave similarly, Exhibits B - D illustrate unexpected results, i.e. that the disintegration time of Porcine Type A that encapsulates omega-3 polyunsaturated fatty acid in free acid form unexpectedly remains stable over time which notably increases its shelf life over at least the shelf life of Bovine Type A gelatin that encapsulate an omega-3 polyunsaturated fatty acid in free acid form.

14. Formation of skin which leads to hardening of gelatins is not observed when the omega-3 polyunsaturated fatty acid is in its ethyl ester form.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that all statements made by me are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001

of Title 18 of the United States Code, and that any willful false statements may jeopardize the validity of any patent resulting there from.

Respectfully submitted,

Date: 15 July 2010

Thomas Buser
Director of New Product Development
Tillotts Pharma AG

EXHIBIT A

1. A soft gelatin capsule comprising Porcine Type A gelatin, said capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form.

wherein the soft gelatin capsule comprising Porcine Type A gelatin exhibits a longer shelf life as compared to soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin,

wherein said soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin contain a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form, and

wherein the shelf life is determined by storing said soft gelatin capsule comprising Porcine Type A gelatin and said soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin for 3 months at a temperature of 40 °C; disintegrating each of the capsules in water at 37°C; and measuring disintegration times of each capsule to determine the shelf life of each capsule.

2. The soft gelatin capsule as claimed in Claim 1 wherein formulation comprises 5, 8, 11, 14, 17-eicosapentaenoic acid (or "EPA") in free acid form.

3. The soft gelatin capsule as claimed in Claim 2 wherein EPA in free acid form is present in an amount of at least 50 wt % of the formulation.

4. The soft gelatin capsule as claimed in Claim 2 wherein EPA in free acid form is present in an amount between from about 50 wt % to about 60 wt % of the formulation.

5. The soft gelatin capsule as claimed in Claim 2 wherein EPA in free acid form is present in an amount of at least about 90 wt % of the formulation.

6. The soft gelatin capsule as claimed in Claim 1 wherein the formulation comprises 4, 7, 10, 13, 16, 19-docosahexaenoic acid (or "DHA") in free acid form.

7. The soft gelatin capsule as claimed in Claim 6 wherein DHA is present in an amount of between from about 20 wt % to about 30 wt % of the formulation.

8. The soft gelatin capsule as claimed in Claim 1 comprising between from about 100mg to about 2000mg of said formulation.

9. The soft gelatin capsule as claimed in Claim 8 comprising about 500mg of said formulation.

10. The soft gelatin capsule as claimed in Claim 9 comprising about 1000mg of said formulation.

11-41. (Cancelled)

EXHIBIT B

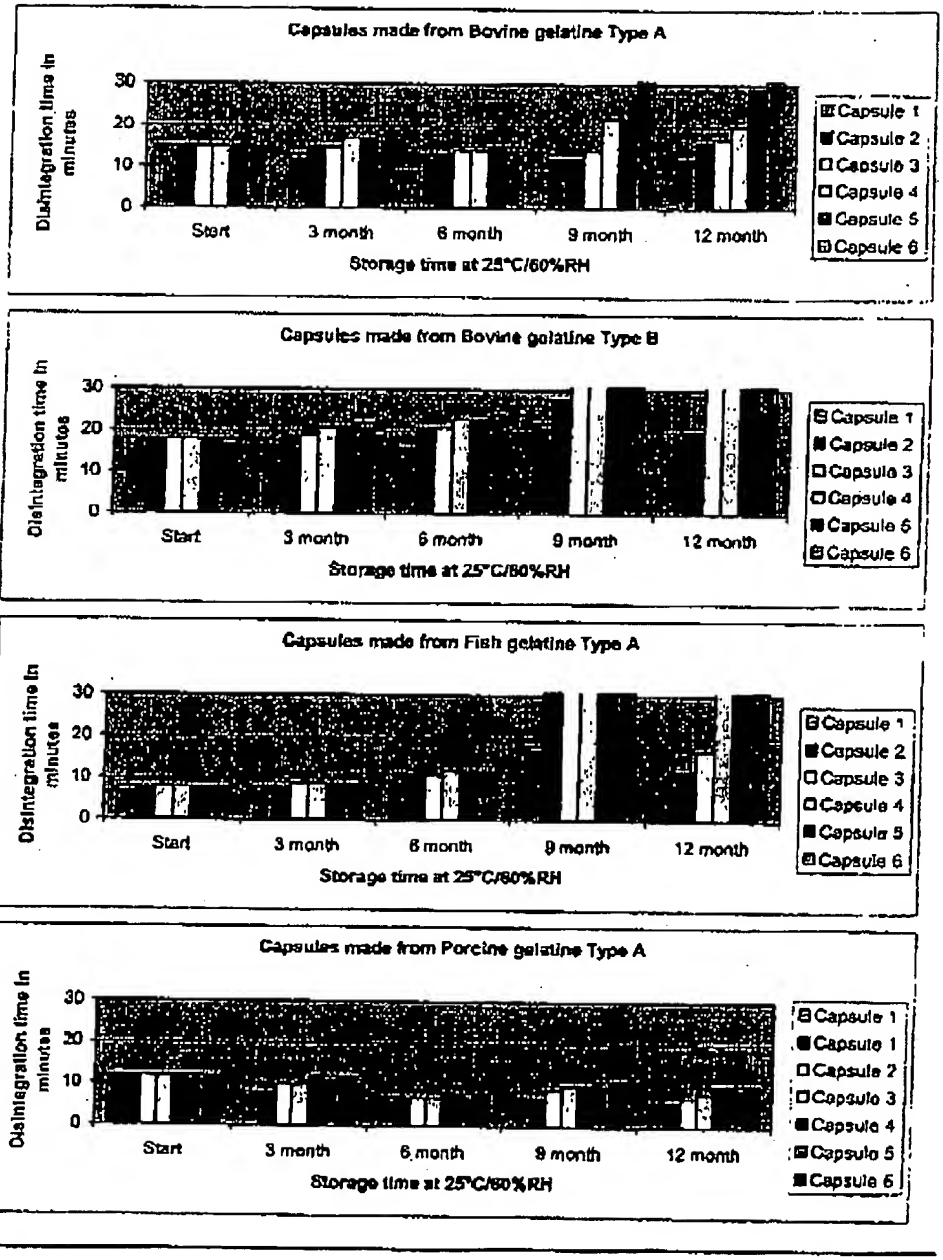
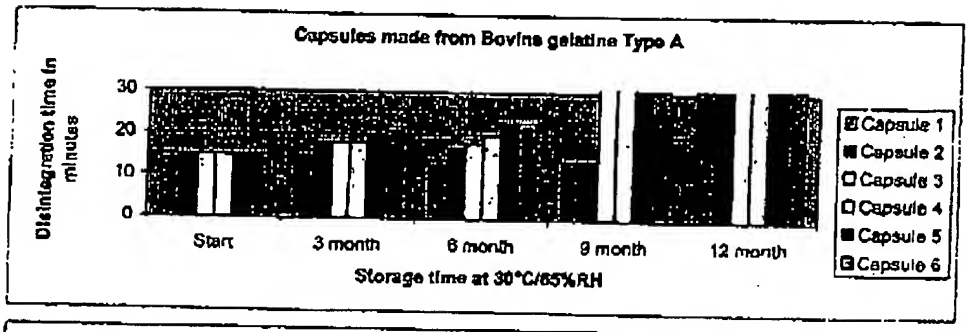
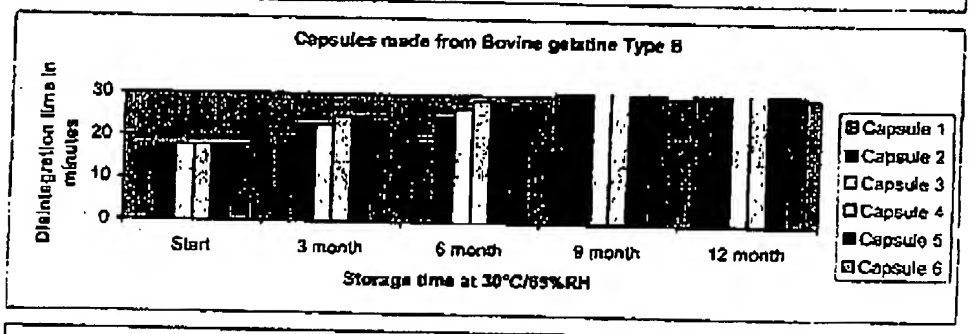
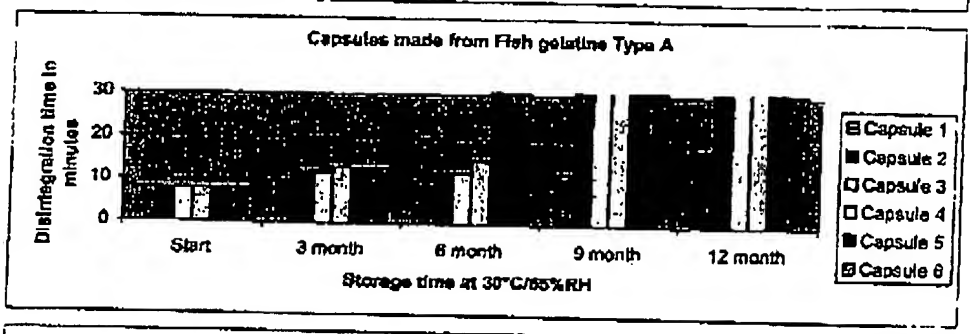

Capsules made from Bovine gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 25°C/60%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Bovine gelatine Type B
Disintegration time in minutes
Start
3 month
6 month
9 month
12 month
Storage time at 25°C/60%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Fish gelatine Type A
Disintegration time in minutes
Start
3 month
6 month
9 month
12 month
Storage time at 25°C/60%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Porcine gelatine Type A
Disintegration time in minutes
Start
3 month
6 month
9 month
12 month
Storage time at 25°C/60%RH
Capsule 1
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6

EXHIBIT C


Capsules made from Bovine gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 30°C/65%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6


Capsules made from Bovine gelatine Type B
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 30°C/65%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6


Capsules made from Fish gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 30°C/65%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6

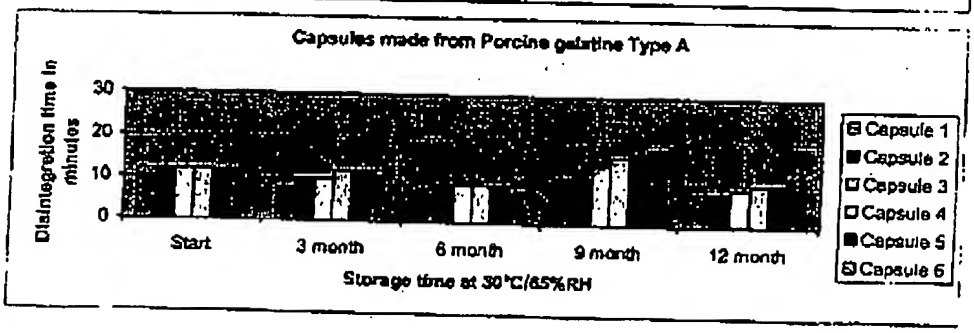
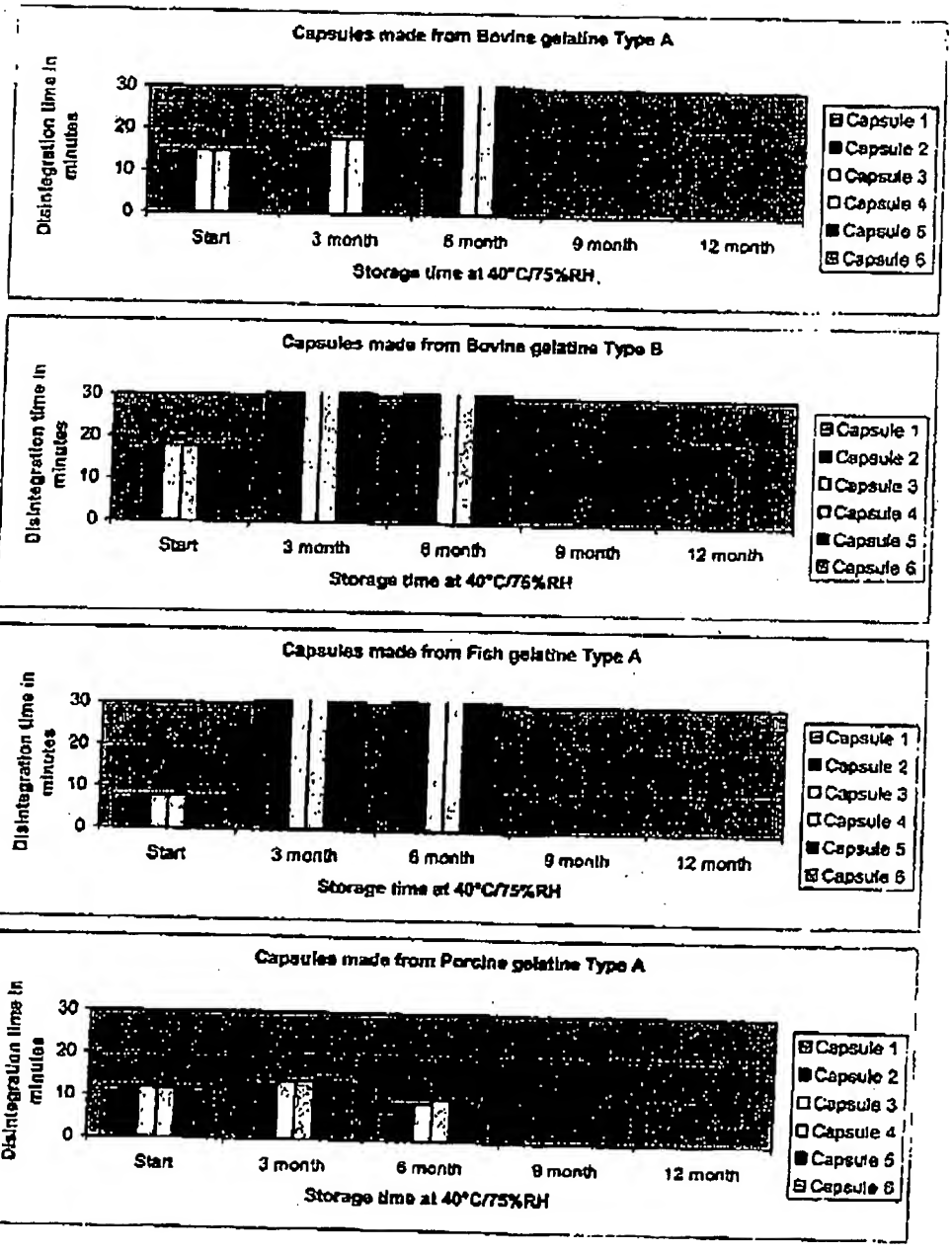

Capsules made from Porcine gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 30°C/65%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6

EXHIBIT D


Capsules made from Bovine gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 40°C/75%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Bovine gelatine Type B
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 40°C/75%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Fish gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 40°C/75%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6
Capsules made from Porcine gelatine Type A
Disintegration time in minutes
30
20
10
0
Start
3 month
6 month
9 month
12 month
Storage time at 40°C/75%RH
Capsule 1
Capsule 2
Capsule 3
Capsule 4
Capsule 5
Capsule 6